

**REMARKS**

Claims 1-13, 33-60 and 67-86 have been withdrawn.

Claim 14 has been amended, and claims 15, 19 and 61-66 have been cancelled by this amendment. No new matter has been added.

Claims 14, 16-18 and 20-32 are now pending in the application.

**Examiner Interview**

Applicants thank Examiner Wright for her time spent on a telephonic interview on November 2, 2007. During that interview, applicants' agent and the Examiner discussed the rejections made by the Examiner with regard to claim 14 and the claims dependent thereon, in the Office Action dated June 27, 2007.

**Claims Rejection – 35 USC § 112**

Claims 14-32 and 61-66 are rejected under 35 U.S.C. 112, first paragraph as based on a disclosure which is not enabling.

The Examiner believes that the composition of a stationary gel is critical or essential to the practice of the invention, but it is not included in the claim(s), thus is not enabled by the disclosure.

Applicants respectfully traverse this rejection.

Of the rejected claims, claims 15, 19 and 61-66 have been cancelled, claim 14 is independent, with the remaining claims dependent thereon.

Amended claim 14 now recites a container comprising among other things:  
*a gel located in the container in contact with a portion of the inner wall,*  
*wherein the gel comprises continuous first and second regions, the first region located at or adjacent to the lower end, and the second region extending upward from a portion of the first region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall, and wherein the first region comprises at least about 80 vol.% of the gel.*

Therefore claim 14 is directed to a specific geometry for a gel disposed in a container which overcomes potential gel movement issues.

Applicants respectfully submit that the test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Teletronics Inc.*, 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988).

One skilled in the art, could refer to the present specification which describes a variety of separator gels that are advantageously used in invention, (see para. [0033]) as acknowledged by the Examiner.

One skilled in the art could also refer to the section of the present specification which describes the desired properties of a gel suitable for use in this invention (see para. [0002] as shown below).

[0002] Fluid collection tubes containing a thixotropic gel for separating phases of different densities, e.g., in blood, are well known. See, e.g., U.S. Patents Nos. 3,997,442, 4,257,886, 4,426,290, 4,770,779, and 6,238,578, the disclosures of which are hereby incorporated by reference. The gel is selected to have a density between that of the phases of blood which are to be separated. Upon centrifugation of a collected blood sample, the force of centrifugation forces the gel from a substantially non-flowing state to a more flowable state. In the flowable state, the gel migrates to a position between the two phases, e.g., between serum and clot portions. And upon cessation of centrifugation, the gel again becomes substantially non-flowable, thereby maintaining the separation between phases. Gel movement, i.e., getting adequate movement of the gel upon centrifugation, can sometimes be an issue. U.S. Patent No. 3,997,442 suggests one solution, but improvements are always desired.

In particular, suitable gel properties are disclosed in US Patent No. US 3,997,442 (see Col. 4 line 55 to Col.5 line 6), US Patent No. US 4,257,886 (see Col. 2 line 65 to Col. 3 line 28), and US Patent No. US 4,426,290 (see Col. 4 line 39 to Col. 8 line 51). Based on these disclosures, applicants submit that one skilled in the art could make and use the claimed invention, without undue experimentation. Thus, claims 14, 16-18 and 20-32 are enabled by the present disclosure as defined by 35 USC § 112, first paragraph.

Claims 14-28, 30-32, 61, and 63-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

The Examiner states; "Claim 14 and 61 broadly recite a gel having a second region extending upward from a portion of the first region of the gel. It is not clear from the claims how the gel provides the necessary rheological properties such a second region extends upward from a portion of the first region without being in the process of being centrifuged."

Applicants respectfully traverse this rejection.

Of the rejected claims, claims 15, 19 and 61-66 have been cancelled, claim 14 is independent, with the remaining claims dependent thereon.

Applicants respectfully submit that the standard for assessing whether a patent claim is sufficiently definite to satisfy the statutory requirement as follows: If one skilled in the art would understand the bounds of the claim when read in light of the specification, then the claim satisfies section 112 paragraph 2. *Exxon Research & Engineering Co. v. United States*, 265 F.3d 1371, 1375, 60 USPQ2d 1272 (Fed. Cir. 2001).

As noted in the specification, those skilled in the art were well aware of the properties of gels, particularly when disposed in containers for phase separation. Thus, there is no clear reason why one skilled in the art would not understand the bounds of the claims; the claims clearly define a container having a gel therein, where the gel has a particular location and geometry.

Thus, applicants submit that one skilled in the art would have no trouble understanding the bounds of claim 14 when read in light of the specification.

In addition "The purpose of claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not 'indefinite' simply because it is hard to understand when viewed without benefit of the specification." *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 1369, 59 USPQ2d 1745 (Fed. Cir. 2001)

For these reasons applicants submits claims 14, 16-18, 20-28, and 30-32 are definite as defined by 35 USC § 112, second paragraph.

### **Claims Rejection – 35 USC § 102**

Claims 14-32 and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,350,593 to Kessler ("Kessler").

Applicants respectfully traverse this rejection in view of the amendment to claim 14.

Of the claims rejected, claims 15, 19 and 61-65 have been cancelled, claim 14 is independent, with the remaining claims dependent thereon.

Amended claim 14 now recites among other things:

*a gel located in the container in contact with a portion of the inner wall, wherein the gel comprises continuous first and second regions, the first region located at or adjacent to the lower end, and the second region extending upward from a portion of the first*

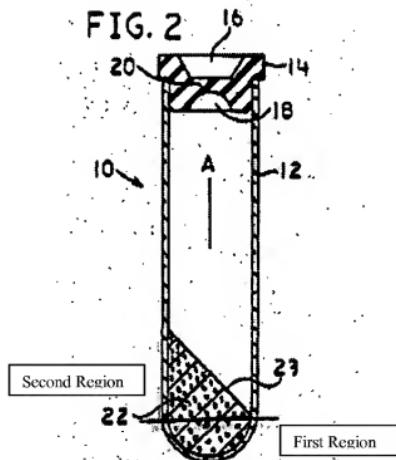
*region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall, and wherein the first region comprises at least about 80 vol.% of the gel.*

The MPEP section 2131 on Anticipation — Application of 35 U.S.C. 102(a), (b), and (c) [R-1] states: **TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM**

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053(Fed. Cir. 1987).

Applicants submit that Kessler fails to disclose at least the claimed feature of the first region comprising at least about 80 vol.% of the gel.

Kessler is silent in regard to the vol% of gel within the first region. In contrast, it can be seen from Figure 2 of Kessler as modified by the Examiner in the Office Action of June 27, 2007 (as shown below) that the majority of the vol.% of the gel is in the second region of the gel.



For this reason, applicants submit that independent claim 14 and dependent claims 16-18 and 20-32, are not anticipated by the Kessler reference.

Furthermore, the invention defined by amended claim 14, is neither taught nor rendered obvious by Kessler. Kessler has no suggestion of the first region of a gel comprising at least about 80 vol.% of the gel and is silent in regard to the amount of vol.% of the gel which should be present in the first region. In fact, Kessler appears to teach away from the first region containing the majority of the gel vol.% as previously shown by Figure 2 of Kessler as modified by the Examiner.

Accordingly, it is submitted that the container as defined by claim 14, is not taught or suggested by Kessler.

### **Conclusion**

In view of the amendment and remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

/Mark Lindsey/

Mark Lindsey  
Registration No. 52,515  
Agent for Applicant(s)  
201 847 6262

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Becton, Dickinson and Company  
1 Becton Drive, MC110  
Franklin Lakes, New Jersey 07417-1880

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